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08/219,200 03/29/94 LINSLEY

ADAMS, P

1811/0913

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09/13/96

COMMISSIONER OF PATENTS AND TRADEMARKS

9-13-96

☒ This application has been examined ☒ Responsive to communication filed on 7/15/96 & 7/19/96 ☐ This action is made final

A shortened statutory period for response to this action is set to expire 3 month(s), 0 days from the date of this letter. Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☐ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice of Draftsman's Patent Drawing Review, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____

Part II SUMMARY OF ACTION

1. ☒ Claims 1, 3-5, 10-12, 40-42, 67-76 & 78 are pending in the application.

   Of the above, claims 67-76 are withdrawn from consideration.

2. ☒ Claims 2, 9-17, 20-39, 43-66 & 77 have been cancelled.

3. ☐ Claims _____ are allowed.

4. ☒ Claims 1, 3-5, 10-12, 40-42, & 78 are rejected.

5. ☐ Claims _____ are objected to.

6. ☐ Claims _____ are subject to restriction or election requirement.

7. ☒ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.

8. ☐ Formal drawings are required in response to this Office action.

9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).

10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).

11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).

12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.

13. ☐ Since this application apppears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

14. ☐ Other

EXAMINER'S ACTION

15. Claims 2, 4, 9-17, 20-39, 43-66 and 77 have been cancelled in response to applicant's amendment.

16. Claims 1, 19, 40, 78 have been amended.

17. Claims 1, 3, 5-8, 18, 19, 40-42, 67-76 and 78 are pending.

18. Claims 67-76 have been withdrawn as directed to a non-elected invention.

19. Claims 1, 3, 5-8, 18, 19, 40-42 and 78 are currently under consideration.

20. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contempletated by the inventor of carrying out his invention.

21. Claims 1, 3, 41, 42 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the use of B7Ig or CD28Ig in a method for inhibiting T cell proliferation, does not reasonably provide enablement for the use of a generic B7/CD28 derivative or a method of inhibiting binding of B7 to CD28. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. With the methods of claims 1 and 3 a method for inhibiting T cell proliferation comprising contacting CD28 positive T cells with B7 antigen will not inhibit proliferation. The system by nature works by contacting CD28 positive T cells with B7 antigen to induce proliferation. Therefore, the claims must define around nature. The method of claims 41 and 42 use CD28 and B7 therefore, it is unclear how the claim is inhibiting CD28 from binding B7. Therefore, the claim should be amended to define around this problem. Regarding the derivatives, the specification does not teach a method of obtaining derivatives other than B7/CD28 Ig fusion proteins which would be useful in the claimed method. It is suggested that the claims be limited to what is specifically enabled by the specification which are Ig fusion proteins. The derivatives language reads on a bivalent construct which includes a B7/CD28 binding moeity and a CD3 binding moeity thereby activating T cell proliferation.

22. The amendment to claim 40 recites "dna" this claim should be amended to read --DNA--.

23. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

24. Claims 19, 40 and 78 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1-8 of U.S. Patent No. 5,434,131. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims are

drawn to a method for treatim immune system diseases mediated by T cell interactions using a fusion protein which contains a portion of the extracellular domain of CTLA4. This CTLA4 fusion protein is substantially similar to the CD28 fusion protein of the claimed invention and therefore the claimed invention is obvious in view of the patented claims.

This is a *provisional* obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

25. Claims 19, 40 and 78 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2 of U.S. Patent No. 5,521,288. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant application is drawn to a method of using a CD28 fusion protein to inhibit binding of B7 to CD28. B7 was known to be the natural ligand for CD28 and therefore a fusion protein as disclosed in both applications would have been used to inhibit B7 binding to CD28. A restriction requirement was not made with respect to the CD28Ig fusion protein and the method of using the fusion protein in the parent application. The method is therefore obvious in view of the fusion protein for the reasons given above.

This is a *provisional* obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

26. Claims 1, 3, 5-7, 17, 18, 41 and 42 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 11, 12 and 17 of copending application Serial No. 08/219,518. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant application is drawn to a method of using a B7 protein to inhibit binding of B7 to CD28. B7 was known to be the natural ligand for CD28 and therefore a fusion protein as disclosed in both applications would have been used to inhibit B7 binding to CD28. A restriction requirement was not made with respect to the B7Ig fusion protein and the method of using the fusion protein in the parent application. The method is therefore obvious in view of the fusion protein for the reasons given above.

This is a *provisional* obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

27. It is acknowledged that applicant contacted the examiner regarding an information disclosure statement (IDS) that was mailed to the Office for this application. Every effort was made to locate this IDS prior to the mailing of this action. However, the IDS was not matched with the application prior to the mailing date of the action. Upon receipt of this action, and before the next response, applicant should contact the examiner at the number below to determine if the Office matched the IDS with the application.

28. No claims allowed.

26. Papers related to this application may be submitted to Group 180 by facsimile transmission. Papers should be faxed to Group 180 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

27. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donald E. Adams whose telephone number is (703) 308-0570. The examiner can normally be

reached Monday through Thursday from 7:30 to 6:00. A message may be left on the examiners voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Christina Chan can be reached at (703) 308-3973. The fax phone number for Group 1816 is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 180 receptionist whose telephone number is (703) 308-0196.

September 12, 1996

Donald E. Adams, Ph.D.
Primary Examiner
Group 1800